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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/137,059	08/20/1998	BRIAN JOHNSTON	A-65200/WH/	2454
25226	7590	11/03/2003	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EPPS FORD, JANET L	
			ART UNIT	PAPER NUMBER
			1635	44
DATE MAILED: 11/03/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/137,059

Applicant(s)

JOHNSTON ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-49 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28 and 32-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

2. The Declaration under 37 CFR 1.132 filed 7-25-03 is sufficient to overcome the rejection of claims 23-26, 28, 32, 34-36 and 38-49 based upon 35 USC § 112, 1st paragraph as set forth in the last Office action.

Election/Restrictions

3. The restriction requirement of 11-06-01 has been reconsidered, claims 27, 33, and 37 will be rejoined with the elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 23-28, 32-49 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a correlation between step (a) and (b) of the method recited in claim 23. Specifically, there should be a correlation between the “catalytic action upon the substrate,” which is indicative of the presence of the target molecule, and the “detection of the presence of the target molecule” as recited in the second step.

The second step renders the claimed method indefinite since it is not apparent that there is a correlation between step (a) and (b). Moreover, the last step of the method recites the phrase “if any.” This phrase questions the presence and/or absence of the target molecule in the

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composition, however the method is directed to a method for detecting the presence of a target molecule, and is not drawn to a method for detecting the presence and/or absence of a target molecule in a composition.

Claim Rejections - 35 USC § 102

6. Claims 23-26 and 28 stand rejected, and claims 27, 33 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Bekkaoui et al. (U.S. Patent 6,136,533) for the same reasons of record as set forth in the Official Action mailed 02/27/02, 12/11/02, and those reasons set forth below.

Applicant's arguments filed 07/30/03 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Bekkaoui et al. does not disclose an allosterically regulated RNA molecule that adopts a catalytically active conformation upon binding to a non-substrate target molecule as presently claimed. First, it is noted that the instant claims do not recite the limitations that Applicants argue are not taught by the Bekkaoui et al. reference. The features upon which applicant relies upon, specifically wherein the RNA molecule is allosterically regulated, are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Moreover, Applicants argue that Bekkaoui et al. does not disclose the claimed element of a catalytically inactive RNA molecule, which comprises a catalytic domain, as required for this reference to be anticipatory. Contrary to Applicant's assertions, Bekkaoui et al. clearly describe methods for detecting a target nucleic acid molecule, in the presence of heterologous nucleic acid molecules in a solution, wherein said method comprises the general steps of providing in the

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solution ribosomal protein, and/or spermine, and/or a chelator and a detergent and under conditions wherein two complementary nucleotide molecules will hybridize, a ribozyme molecule, a labeled co-target nucleic acid molecule and the target nucleic acid molecule, wherein the co-target and the target molecules have different sequences and wherein the ribozyme molecule comprises two regions complementary to portions of the co-target and target nucleic acid molecules, wherein the first portion is present on the labeled co-target nucleic acid molecule which contains a cleavage site for the ribozyme and the second portion is present on the target nucleic acid molecule, wherein the complementary regions include at least the minimum number of complementary nucleotides to obtain hybridization between the ribozyme molecule and the co-target and target nucleic acid molecules, allowing the ribozyme molecule to react with the labelled co-target nucleic acid molecule, which contains the ribozyme cleavage site, and **detecting the presence** of free label when the target nucleic acid molecule is present in solution as compared with when the target nucleic acid molecule is not present in solution (see col. 13, lines 45-67).

This portion of Bekkaoui et al. clearly anticipates the method steps of the claimed invention, since the method comprises binding of a ribozyme with a target molecule that lacks a ribozyme cleavage site, therefore although the ribozyme binds to the target molecule, it does not display any catalytic activity on the target nucleic acid molecule that lacks the cleavage site. However, upon binding of the ribozyme/target molecule complex with the labeled co-target comprising a cleavage site, the ribozyme portion of the complex exhibits cleavage action on the co-target comprising the cleavage site, and the free label from the cleaved co-target is then detected.

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7. Claims 23-26, 32, 38-40 stand rejected, and claims 27, 33 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stefano et al. (U.S. Patent 5,472,840) for the same reasons of record as set forth in the Official Action mailed 02/27/02, 12/11/02, and those reasons set forth below.

Applicant's arguments filed 07/29/02 have been fully considered but they are not persuasive. First, Applicants traverse the instant rejection by arguing that what is described in Figure 1, does not include a catalytically inactive RNA molecule that comprises a catalytic domain. Contrary to Applicant's assertions, the RNA target molecule 11 of Figure 1A of Stefano comprises a region 29 that forms the catalytic region of a ribozyme, once bound to the first nucleic acid 31. Additionally, the first nucleic acid also comprises an autocatalytic replication region, wherein said region does not become activated until the first nucleic acid is bound to the target, wherein a ribozyme is formed, and said ribozyme (once exposed to divalent cation, Mg^{+2}) becomes active, cleaves at position 39, and releases the autocatalytic replication region from said first nucleic acid. The presence of the RNA target molecule in a composition is determined by monitoring for the presence of the autocatalytic replication reaction product, which is indicative of the presence of the target molecule.

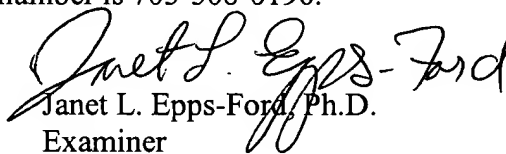
Therefore, contrary to Applicant's assertions, the teaching of Stefano does provide a method that includes target-dependent activation of a catalytically inactive RNA molecule comprising a catalytic domain.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
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